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EXAMINER

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1617

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 09/738,212
Filing Date: December 15, 2000
Appellant(s): NEUER ET AL.

Paper No. 14

mailed out
date. 1-15-03

Gabriel Lopez
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 16, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

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(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 21-30 and 33 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,047,396 A	ORBAN et al.	9-1991
5,342,625 A	HAUER et al.	8-1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the appellant regards as his invention.

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Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

Claim 33 is vague and indefinite because it is unclear what appellant intends to claim for component (e). Is component (e) either a combination of ricinoleic acid glyceride(s) and multiply unsaturated fatty acid glycerides or castor oil or is it a mixture of ricinoleic acid glyceride(s) with multiply unsaturated fatty acid glycerides or a mixture of ricinoleic acid glyceride(s) with castor oil? Additionally, in relation to what are the proportions of multiply unsaturated fatty acid glycerides smaller?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,047,396 (396) in combination with US 5,342,625 (625).

US '396 discloses a pharmaceutical composition comprising 1 part cyclosporin, 8 to 13 parts of a polyethylene glycol saturated hydroxy fatty acid, and 4 to 10 parts of a mono- or polyvalent alcohol (abstract). Cyclosporin A is disclosed at column 2, lines 44-47. Alcohols that may be present as co-solvents in the composition are ethanol and propylene glycol (col. 3, lines 1-5). Various excipients can be used in the formulation (col. 3, lines 15-16). Example 1 teaches 65 g of Solutol® HS 15 (polyethylene glycol-

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660-12-hydroxystearate), 30 ml of ethanol and 5 g of cyclosporin A. Ethanol is added to 100 ml. The composition of example 1 comprises 65% polyethylene glycol-660-12-hydroxystearate, 5% cyclosporin A and 30% ethanol. See also claim 6 for polyethylene glycol-660-12-hydroxy stearate and claim 7 for ethanol and propylene glycol. US '396 does not teach the composition in a capsule.

US '625 is directed to pharmaceutical compositions comprising cyclosporins (title). For Cyclosporin A and additional cyclosporins, see column 2, line 61 to column 3, line 15. The composition comprises a hydrophilic phase, a lipophilic phase and a surfactant (col. 6, lines 45-50). For propylene glycol as the hydrophilic phase, see column 7, lines 21-25. For additional alcohols in the hydrophilic phase such as ethanol, see column 8, lines 25-35. For polyoxyethylene stearic acid esters as surfactants, see column 9, lines 40-44 and column 10, lines 31-32. US '625 teaches at column 12, lines 16-17 that the composition may contain a single surfactant, i.e. a polyoxyethylene stearic acid ester. For hard and soft gelatin capsules, see column 16, lines 25-28. For ratios of components, see column 17, line 50 to column 18, line 20. The ratio of cyclosporin (a) to hydrophilic phase (c) is 1:0.2-10 p.p.w. (col. 17, lines 50-54). The ratio of cyclosporin to surfactant (b) is 1:0.5-20 (col. 18, lines 13-20). Therefore, the ratio of (a):(b):(c) is 1: 0.5-20: 0.2-10, which overlaps the instantly claimed ratios. US '625 teaches fatty acid triglycerides (triesters of fatty acids) as the lipophilic phase at column teaches fatty acid triglycerides (triesters of fatty acids) as the lipophilic phase at column 8, lines 56-65 and mono-, di- and mono/diglycerides as surfactants at column 11, lines 36-52.

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US '396 teaches a composition containing cyclosporin A, polyethylene glycol-660-12-hydroxystearate, ethanol and propylene glycol. US '625 teaches that compositions containing a cyclosporin, a polyethoxylated hydroxy fatty acid ester surfactant, ethanol and propylene glycol can be provided in a hard gelatin capsule.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '396 in a hard gelatin capsule as taught by US '625 with the reasonable expectation of obtaining a cyclosporin composition that provides convenient oral administration and improved bioavailability.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690400. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to compositions comprising cyclosporin, a C₂-C₃ alcohol and a surfactant. The

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applications differ in that 09/690400 is claiming also a mixed mono-, di-, triglyceride. The instant application discloses mono-, di-, and triesters of fatty acids for use in the compositions. See claim 3. Glycerides are esters. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the composition of the instant application and add mixed mono-, di-, triglyceride as disclosed in 09/690,400 expecting to obtain a oral dosage form containing cyclosporin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin a polyethoxylated hydroxy fatty acid ester surfactant and an alcohol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547802. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin, an alcohol and a surfactant.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(11) Response to Argument

Appellant argues that it is clear from instant claim 33 that optional component (e) is either ricinoleic acid glycerides(s) with multiply unsaturated fatty acid glycerides or ricinoleic acid glycerides(s) with castor oil. It is the Examiner's position that a fair reading of this claim does not provide a clear and concise depiction of Appellant's intention. It is not clear if component (e) can be ricinoleic acid glycerides(s) with castor oil or castor oil alone. Appellant's intent is unclear. It appears that this may be a situation where a broad limitation is claimed together with a narrow limitation. See *ex Parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303. The Board stated that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required or (b) a required feature of the claim. In this instance, claim 33 recites the broad limitation castor oil and also recites the narrower limitation ricinoleic acid glycerides. The chief constituent of castor oil is ricinolein (glyceride of ricinoleic acid). Therefore, the incorporation of castor oil into the composition would include the incorporation of ricinoleic acid glycerides.

Appellant argues that it is clear from instant claim 33 that the unsaturated fatty acid glycerides are present in an amount lesser than ricinoleic acid glyceride(s). It is the Examiner's position that this is not clear from a fair reading of the instant claim. The

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amount of unsaturated fatty acid glycerides could be in relation to any other component in the composition. The claim is indefinite.

In response to appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '396 teaches the composition instantly claimed, albeit for injection, and US '625 teaches that compositions like those disclosed in US '396 are useful for oral administration and can be provided in hard gelatin capsules. US '396 also teaches at column 1 that it is known in the art to orally administer cyclosporin. The motivation to combine the references is to provide convenient oral administration of a cyclosporin composition.

Appellant argues that there is no motivation to use the compositions of US '396 for oral administration. The instant invention is drawn to a product. The future intended use of that product does not provide patentability to the claims. Terms merely setting forth an intended use for, or a property inherent in, an otherwise old composition do not differentiate the claimed composition from those of the prior art. *In re Pearson*, 181 USPQ 641. Difference in use cannot render claimed composition novel. *In re Tuominen*, 213 USPQ 89. As stated above, US '396 teaches the composition instantly claimed. US '625 teaches that compositions like those disclosed in US '396 can be provided in hard

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gelatin capsules. The prior art teaches that compositions containing the same components as instantly claimed can be provided in hard gelatin capsules.

Appellant argues that US '396 does not teach the additional component of instant claim 33, mono-, di- and/or triesters of fatty acids. This argument is not convincing because US '625 teaches that monoglycerides, diglycerides and triglycerides of fatty acids, which are esters of fatty acids and glycerol, can be used alone or in combination in cyclosporin pharmaceutical compositions. Thus, US '625 makes up this deficiency in US '396.

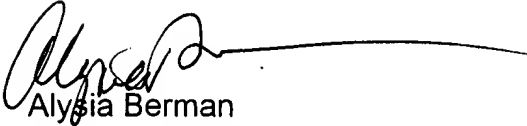
In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the prior art teaches all of the limitations instantly claimed.

Appellant argues that the double patenting rejections are provisional and cannot be resolved until allowability is indicated. Because Appellant has not provided any substantive arguments why the double patenting rejections are improper, they are maintained.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



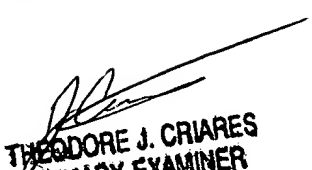
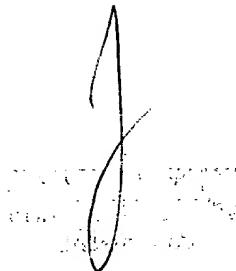
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